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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,850	09/19/2001	Waltraud Ankenbauer	5304	4731

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ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
1145 ATLANTIC AVENUE
ALAMEDA, CA 94501

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,850	Applicant(s) ANKENBAUER ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 19 is/are rejected.
- 7) ☒ Claim(s) 5-7, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

J/K

DETAILED ACTION

This Office Action is responsive to the Amendment received on December 15, 2004.

Preliminary Remark

The Office acknowledges the addition of claims 18 and 19.

Claims 5-7, 18, and 19 are pending and are under prosecution therefore.

Claim Objections – Necessitated by Amendment

Claims 5-7, 18, and 19 are objected to because of the following informalities: claims recite the term, “*Archaeoglobus fulgidis*” when the instant specification recites the term, “*Archaeoglobus fulgidus*.” Consistency in term usage is suggested.

Claim Rejections - 35 USC § 102

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (Nucleic Acids Research, 1997, vol. 19, no. 9, page 2511), made in the Office Action mailed on June 15, 2004 is withdrawn in view of the Amendment received on December 15, 2004, amending the claims to become drawn to a thermostable *Archaeoglobus fulgidus* enzyme exhibiting 3’-5’ exonuclease activity.

Claim Rejections - 35 USC § 112

Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites that the first thermostable *Archaeoglobus fulgidus* enzyme is SEQ ID NO: 21.

Applicants are reminded that SEQ ID NO: 21, which was published in the WO document, which corresponded to the above enzyme, had been amended to become SEQ ID NO: 18 in the instant application. The CRF entered into the PTO Sequence Database reflects this change.

Therefore, it becomes indefinite as to what the nature of the above enzyme.

Amending the claim to recite SEQ ID NO: 18 would overcome this rejection.

Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 5-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on June 15, 2004 is maintained for the reasons of record.

While claims have been amended to embrace a subgenus, the usage of a first *Archaeoglobus fulgidus* enzyme exhibiting 3'-5' exonuclease activity but essentially no DNA polymerase activity, claims continue to fail to describe the plurality of species of embraced by the subgenus claims for the following reasons.

The claims as amended embraces all exonucleases that meet the requisite characteristic of exhibiting 3'-5' exonuclease activity but essentially no DNA polymerase activity. The specification even disclose that, "the enzyme that was found to be suitable for this task is e.g., *exonuclease III*," (page 4, 2nd paragraph), wherein the specific species from which said exonuclease was isolated from was the strain VC-16 (page 12, *Example 1*) the claims nevertheless, embraces all exonuclease isolated from any strain of *Archaeoglobus fulgidus* having the requisite characteristics.

While the rejection is maintained under the same statute, Applicants' amendment necessitates the citation of the below references.

Nilsen et al. (Applied and Environmental Microbiology, May 1996, vol. 62, no.5, pages 1793-1798) disclose a different strain of *Archaeoglobus fulgidus*, strain 7324 (DSM 8774) (page 1795, Table 2), evidencing the presence of different strains within the subgenus of *Archaeoglobus fulgidus* species.

In addition, the instant specification discloses that the exonuclease of the invention is isolated from VC-16 strain was disclosed by Klenk et al. (page 12, bottom paragraph).

Klenk et al. (Nature, 1997, vol. 390, page 364-370) disclose that *Archaeoglobus fulgidus* contains 2,436 open reading frames (Abstract). The artisans also state that a quarter of (651 ORF) *Archaeoglobus fulgidus* encodes functionally *uncharacterized* proteins while the other quarter of the genome encodes new proteins indicating substantial archaeal gene diversity. Hence, out of the 2,346 open reading frames, each of which encoding different proteins, the artisans clearly indicate that there remains uncharacterized proteins encoded by the subgenus *Archaeoglobus fulgidus*.

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Further, the instant specification discloses that a single set of primers (SEQ ID NO: 1 and 2), which were complementary to the N- and C- terminus of the *Archaeoglobus fulgidus* exonuclease III gene (page 13, *Example II*). No other primer sets were disclosed for isolating/amplifying the exonuclease of the requisite characteristics from other strains of *Archaeoglobus fulgidus*.

Therefore, it is determined that of exonuclease enzyme of the instant specification, an enzyme of SEQ ID NO: 17¹, isolated from VC-16 strain of *Archaeoglobus fulgidus* would not demonstrate a representative number of species of enzymes encoded by the subgenus of *Archaeoglobus fulgidus*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9, 10, and 12 of copending Application No. 10/903,992 (hereto referred to as the '992 application). Although the

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conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 5-7 of the instant application are drawn to a composition comprising a first thermostable *Archaeoglobus fulgidus* enzyme exhibiting 3'-5' exonuclease activity but essentially no DNA polymerase activity and a second enzyme exhibiting DNA polymerase activity, an embodiment of which is drawn to the second enzyme being *Taq* polymerase.

Claims 7 and 10 of the '992 application is drawn to a composition/kit comprising a thermostable double strand dependent 3'-5' exonuclease and a thermostable DNA polymerase, wherein claims 9 and 12 further define said first enzyme as an exonuclease III.

While claims 7, 9, 10, and 12 do not explicitly state that the first enzyme is from *Archaeoglobus fulgidus* or that the second enzyme is a *Taq* polymerase, the instant specification clearly discloses that the composition of the invention would be a thermostable enzyme obtainable from *Archaeoglobus fulgidus*, which catalyzes the degradation of mismatched ends of primers or polynucleotides in the 3' to 5' direction and that this enzyme would support DNA polymerases like *Taq* in performing DNA synthesis at low error rates and synthesis of products of more than 3kb on genomic DNA [0025] and [0106].

Therefore, claims 5-7 are obvious over claims 7, 9, 10, and 12 of the '992 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

¹ See discussion under 112, second paragraph.

Conclusion

No claims are allowed.

Applicants are advised that U.S. Serial No. 10/192,902 is filed by at least one common inventor as the instant application. While the instant claims have not yet been provisionally rejected over the above-recited application, as the instant claims are species in nature, Applicants are advised that should the application become amended during prosecution to become overlapping, a non-statutory obviousness double patenting rejection would be applied.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

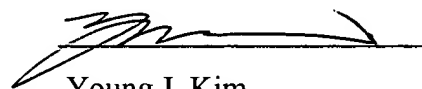
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The

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Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

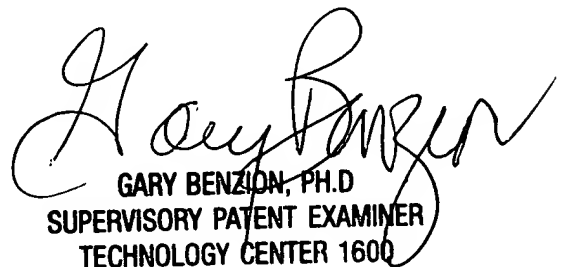
Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
3/22/05

**YOUNG J. KIM
PATENT EXAMINER**

yjk



**GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**